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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/850,353	05/02/1997	YESOOK KIM	PC9563JTJ	4835

23913 7590 02/24/2006

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EXAMINER

WHITE, EVERETT NMN

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/850,353	Applicant(s) KIM, YESOOK	
	Examiner Everett White	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/24/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed November 14, 2005 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Claims 1, 2 and 4-15 have previously been canceled;
 - (B) Claim 16 has been added;
 - (C) Comments regarding Office Action have been provided drawn to:
 - (I) 112, 2nd paragraph rejections, which have been withdrawn;
 - (II) 102(a) rejection, which has been maintained for the reasons of record.
2. Claims 3 and 16 are pending in the case.
3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

4. Claims 3 and 16 stand rejected under 35 U.S.C. 102(a) as being anticipated by Chiese et al (US Patent No. 5,773,029) for the reasons disclosed on pages 3-5 of the Office Action mailed November 20, 2003.

Applicant's arguments filed November 11, 2005 have been fully considered but they are not persuasive. Applicants' arguments presented on pages 7-10 of the response have been carefully considered, but are not persuasive in view of the broadness of the instantly claimed invention. The claims of the instant method set forth a series of tasks, but do not disclose details of how the tasks are performed. No specific compound or salt thereof has been disclosed in the instant claim, nor does the instant methods set forth the desired target solubility. Applicants argue that the Chiesi et al patent does not describe in any detail a method to determine a useful salt among a series of salts as discussed and claimed in Applicant's pending application. This argument is not persuasive because the Chiesi et al patent does set forth various drugs, which are well known in the art, including their therapeutic efficacy or the dose that may be administered to a patient to treat a particular condition. See column 3, 2nd paragraph for a list of acidic drugs that include oxicans, hypoglycemic sulfonylureas,

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benzothiadiazine diuretics, barbituric acids, arylacetic and arypropionic anti-inflammatory acids. Also see Examples 1-11 and Tables 1-6, which set forth well known acidic drugs, salts thereof, and complexes thereof with cyclodextrins. The solubility is calculated in some of the Examples and Tables of the Chiesi et al patent (e.g., see examples 9-11 and Tables 1-6). The Chiesi et al patent does set forth information, which expressly or inherently anticipate the instantly claimed invention. Accordingly, the rejection of Claims 3 and 16 under 35 U.S.C. 102(a) as being anticipated by the Chiese et al patent is maintained for the reasons of record.

Summary

5. Claim 3 and 16, the only pending claim of record, are rejected.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

7. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-

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0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (571) 272-0661. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



E. White



James O. Wilson
Supervisory Primary Examiner
Technology Center 1600